

Group I, claims 19-21, 23-38, 40 and 41, with traverse. As indicated in the Office Action, the subject matter of Group III, claims 43-69 has been rejoined in the present application. Thus, only the subject matter of Group II, claims 22, 39 and 42, is withdrawn from consideration.

Applicants respectfully submit that the restriction between Group I and Group II is improper under PCT standards. In particular, as discussed in MPEP §1850A, unity of invention is considered only in relation to the independent claims. By dependent claims is meant a claim that contains all of the features of another claim and is in the same category of claims as the other claim. Claim 22 depended from and was in the same category as claim 19; claim 39 depended from and was in the same category as claim 37; and claim 42 depended from and was in the same category as claim 40. Therefore, the Restriction Requirement is improper and should be withdrawn.

Claims 19-21, 23-38, 40, 41, 46-66 and 68 are rejected under 35 U.S.C. §102 over Lindenbaum (U.S. Patents Nos. 5,461,030 and 5,591,709, hereinafter Lindenbaum '030 and Lindenbaum '709, respectively). Claims 19-21, 23-38, 46-64 and 68 have been canceled. With regard to claims 40, 41, 65 and 66, and the claims dependent thereon, Applicants respectfully traverse the rejection.

The present invention is particularly directed to cosmetics that comprises a complete nutrient medium that supports viable *in vitro* growth of human epidermal keratinocytes, and their use in a cosmetic treatment. As discussed in the specification, the use of a complete nutrient medium is considerably advantageous for improvement of the viability and maintenance of the integrity and balance of the superficial cells of the skin. In particular, it enables the primary intrinsic qualities of the skin to be preserved on a long-lasting basis and its resistance to damage to be increased. Page 3, lines 28-37. Applicants are not aware of any teaching in the prior art of the use of a complete nutrient medium in cosmetics.

Claims 40 and 65 are directed to a method of cosmetic treatment. Lindenbaum does not teach or suggest any cosmetic treatment using the product described therein. To emphasize the cosmetic focus of the claims, the claimed method comprises "contacting only an area of human skin whose integrity has not been breached by injury with a composition . . ." Lindenbaum does not teach or suggest contacting only an area of human skin whose integrity has not been breached by injury with the composition disclosed therein. In particular, Lindenbaum specifically teaches using the compositions "for promoting wound healing of skin." Col. 1, lines 7-9, of Lindenbaum '030. In addition, Lindenbaum teaches that the term "wound" is defined as "a breach in the continuity of skin tissue which is caused by direct injury to the skin." Col. 3, lines 12-14, of Lindenbaum '030. Lindenbaum goes on to recite that "[s]kin wounds are generally characterized by several classes: punctures, incisions, excisions, lacerations, abrasions and burns." Col. 3, lines 14-16.

As discussed in the interview, skin that is not wounded may still not be perfectly unblemished. However, the recitations of claims 40 and 65 do not require perfectly unblemished skin. Instead, claims 40 and 65 recite that the "integrity" of the skin has not been breached. As used in the specification, at page 3, lines 30-33, the term "integrity" is clearly directed to the cosmetic aspects of the composition. One of ordinary skill in the art is well aware that skin is generally not perfectly unblemished. Thus, one of ordinary skill would understand the phrase "whose integrity has not been breached . . ." to include skin that is not perfectly unblemished but to exclude skin that has been wounded, in contrast to the wounded skin addressed in Lindenbaum.

Lindenbaum is not directed to cosmetics or cosmetic methods at all. It is clearly directed to wounded skin, not merely skin that is not perfectly unblemished. In particular, as discussed above, the term "wound" is defined as "a breach in the continuity of skin tissue which is caused by direct injury to the skin" (emphasis added). Direct injury to the skin

refers to something more than mere imperfect skin. In addition, Lindenbaum clarifies its limitation to wound treatment with, examples of wounds, namely punctures, incisions, excisions, lacerations, abrasions and burns. Thus, it is clear from Lindenbaum that this reference does not suggest using this product as a cosmetic on skin that is merely not perfectly unblemished. Instead, Lindenbaum specifically teaches using the composition as a medical treatment on wounded skin.

As also discussed at the interview, Lindenbaum teaches that "the function of the nutrient medium is to provide nutrients to normal, distressed and injured cells which surround or comprise the wound to be treated in order to enhance the growth and repair mechanisms which are responsible for the healing of the wound." Col. 5, lines 23-28, of Lindenbaum '030. Thus, Lindenbaum suggests that the nutrient medium may contact an area of the skin that is not wounded. However, Lindenbaum does not teach or suggest "contacting only an area of human skin whose integrity has not been breached..." with the composition. In particular, Lindenbaum teaches that the purpose of the nutrient medium is "to enhance the growth and repair mechanisms which are responsible for the healing of the wound." It does not teach or suggest applying the composition to maintain integrity of the skin. Thus, there would have been no motivation based on Lindenbaum to contact the composition taught therein only with an area of human skin whose integrity has not been breached.

Claims 112-114 are similar to claims 40 and 65. Claim 112 and 113 correspond to claims 40 and 65, respectively, except that they recite "by a wound" rather than "by injury." Claim 114 corresponds to claim 40 except that it further defines the organic component as promoting cell growth. Claims 112-114 are patentable over Lindenbaum for the same reasons as claims 40 and 65.

Claim 96 recites a cosmetic composition comprising a complex nutrient medium comprising various specifically recited components in specifically recited concentrations.

Lindenbaum does not teach or suggest a composition having these components in these concentrations.

Lindenbaum does not teach a method of cosmetic treatment comprising contacting only an area of human skin whose integrity has not been breached with the composition taught therein. In addition, Lindenbaum does not teach the composition of claim 96. Therefore, the rejection under 35 U.S.C. §102 over Lindenbaum should be reconsidered and withdrawn.

Claims 19, 24-27, 34, 37, 40, 41, 43, 44, 46, 48-51, 61, 65-67 and 69 are rejected under 35 U.S.C. §102 over Wille (U.S. Patents Nos. 5,292,655 and 5,686,307, hereinafter Wille '655 and Wille '307, respectively). Claims 19, 24-27, 34, 37, 43, 44, 46, 48-51, 61, 67 and 69 have been canceled. With regard to claims 40, 41, 65 and 66, the claims dependent thereon, as well as new claims 112-114, Applicants respectfully traverse the rejection.

Wille is directed to methods and formulations for the *in vitro* formation of a histologically complete human epidermis. See the Abstract. Wille does not teach or suggest a method of cosmetic treatment comprising contacting an area of human skin with the composition recited therein. At the end of Wille, Wille teaches that the media and processes have various applications including the production of products for the abolition and/or prevention of wrinkles. Col. 23, lines 29-36, of Wille '655. When this section is reviewed in the context of Wille, which repeatedly and even insistently emphasizes that the purpose of the media is to generate an epidermis *in vitro*, it is clear that Wille is discussing using the epidermis created therein to test products for the abolition and/or prevention of wrinkles. There is no suggestion of contacting the media disclosed in Wille with human skin to abolish or prevent wrinkles.

As noted above, claim 96 recites a particular composition. Wille does not teach or suggest a composition having this composition. In particular, Wille teaches a composition

having "critical component concentrations" including: HEPES at 14-22mM; NaCl at 90-140mM; low Ca^{2+} at 0.03-0.3mM; and six key amino acids having the following

concentrations, Histidine= $1.0-2.5 \times 10^{-4}\text{M}$; Isoleucine= $0.5-5.0 \times 10^{-4}\text{M}$;

Methionine= $1.0-5.0 \times 10^{-4}\text{M}$; Phenylalanine= $1.0-5.0 \times 10^{-4}\text{M}$; Tryptophan= $0.5-5.0 \times 10^{-4}\text{M}$; and

Tyrosine= $1.0-5.0 \times 10^{-4}\text{M}$. Col. 3, lines 22-34, of Wille '655. The composition recited in

claim 96 differs from this composition in at least six ways. In particular, the composition of

claim 96 has more HEPES than the range recited in Wille; the composition of claim 96 has

less Isoleucine than the range recited in Wille; the composition of claim 96 has less

Methionine than the range recited in Wille; the composition of claim 96 has less

Phenylalanine than the range recited in Wille; the composition of claim 96 has less

Tryptophan than the range recited in Wille; and the composition of claim 96 has less Tyrosine

than the range recited in Wille. Attached hereto is a Concentration Table, which compares

the concentrations of these components to Wille, as well as to Lindenbaum. As can be seen

therein, the concentrations of these components are outside of the ranges recited in Wille.

Wille does not teach a method for cosmetic treatment comprising contacting an area of human skin with the composition recited therein. In addition, Wille does not teach the composition of claim 96. Therefore, the rejection under 35 U.S.C. §102 in view of Wille should be reconsidered and withdrawn.

Claims 19-21, 23-38, 40, 41 and 43-69 are rejected under 35 U.S.C. §103 over the combination of the Lindenbaum patents and the Wille patents in view of Cuca. Applicants respectfully traverse the rejection.

For the reasons discussed above, neither the Lindenbaum patents nor the Wille patents teach or suggest the present invention. Cuca does not overcome the deficiencies thereof. Cuca is directed to delivery systems for topical preparations that are commercially stable. The emulsions are water-in-oil. See the Abstract. Cuca does not teach or suggest using a

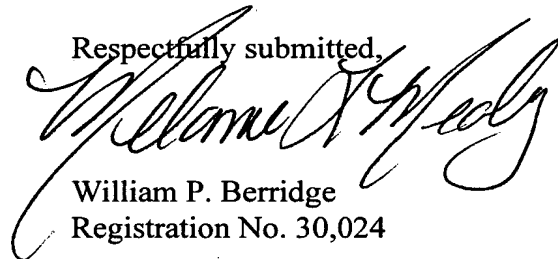
composition within the recitations of claims 40 and 65 in a cosmetic treatment comprising contacting only an area of human skin whose integrity has not been breached with such a composition. In addition, Cuca does not teach or suggest the composition of claim 96.

Therefore, the rejection under 35 U.S.C. §103 should be reconsidered and withdrawn.

In view of the above amendments and remarks, it is respectfully submitted that the above-identified patent application is in condition for allowance. Favorable consideration and prompt allowance are therefore respectfully requested.

Should the Examiner believe anything further is necessary in order to place the application in condition for allowance, she is invited to contact Applicants' undersigned representative at the telephone number listed below.

Respectfully submitted,



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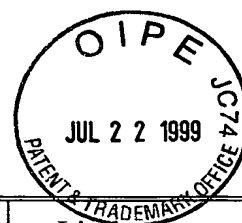
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Attachment:
Concentration Table

CONCENTRATION TABLE



	Claim 96		Wille	Lindenbaum
	mg/l	M	M	M
HEPES	6600.0	2.8×10^{-2}	$1.4-2.2 \times 10^{-2}$	2.8×10^{-2}
Isoleucine	6.0	4.6×10^{-5}	$0.5-5.0 \times 10^{-4}$	1.5×10^{-5}
Methionine	13.5	9.0×10^{-5}	$1.0-5.0 \times 10^{-4}$	3.0×10^{-5}
Phenylalanine	10.0	6.0×10^{-5}	$1.0-5.0 \times 10^{-4}$	3.0×10^{-5}
Tryptophan	9.3	4.6×10^{-5}	$0.5-5.0 \times 10^{-4}$	1.5×10^{-5}